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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,178	06/02/2006	Kab-Sig Kim	5656BIO-1	3197
22442	7590	08/03/2010	EXAMINER	
SHERIDAN ROSS PC 1560 BROADWAY SUITE 1200 DENVER, CO 80202				DICKINSON, PAUL W
ART UNIT		PAPER NUMBER		
1618				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/596,178	KIM, KAB-SIG	
	<b>Examiner</b>	<b>Art Unit</b>	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) 5-7 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-4 and 8-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/2/2006</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election with traverse of Group I in the reply filed on 4/26/2010 is acknowledged. The traversal is on the ground(s) that the cited art does not make nanoscale or amorphous particles and therefore cannot anticipate the claims nor break the unity of the invention.

This is not found persuasive. US 6471993 ('993) discloses a method for preparing a polymer matrix comprising the steps of (1) preparing a mixture comprising one or more active ingredients and a solid porogen (see abstract; col 4, lines 60-3; col 6, lines 17-21) and (2) extracting the solid porogen with an appropriate means to form a resulting matrix (see col 11, lines 62-67). The method makes a polymer matrix. One possible porogen are triglycerides (see col 13, lines 40-48; Table 1). One possible porogen extraction means is extraction by supercritical carbon dioxide (see col 11, lines 62-67). Although '993 does not explicitly teach using supercritical carbon dioxide to extract triglycerides, US 20060035350 ('350) teaches that supercritical carbon dioxide is a common solvent for triglycerides (see paragraph 9). Accordingly, it would have been obvious to use supercritical carbon dioxide to extract triglyceride porogens in the method of '993. The resulting method would be a method comprising the steps of (1) preparing a mixture comprising one or more active ingredients and solid fat and (2) pressurizing the mixture comprising one or more active ingredients and solid fat to the critical pressure or more by adding the gas of a supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat together with

the gas of a supercritical fluid. Thus, the method that is rendered obvious by '993 in view of '350 is identical to Applicant's method in instant claim 1. Regarding the limitation "for preparing nanoscale or amorphous particles", this does not require the particles to have any particular size or composition, other than they must be either nanoscale or amorphous. The matrix of '993 as a whole could be considered as a particle, and this matrix is amorphous. In another interpretation, polymer particles may be used in preparing the matrix and it is reasonable that at least a portion of the polymer particles remains particular when the method is finished. Such particles would be non-crystalline (amorphous). '993 also teaches adding several additive particles into the matrix (see '993, entire document). There only needs to be two nanoscale or amorphous particles present in the final product to read on "a method for preparing nanoscale or amorphous particles".

The requirement is still deemed proper and is therefore made FINAL.

### ***Claim Objections***

Claim 1 is objected to because of the following informalities: Claim 1 is missing a period. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112, Scope of Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 and 8-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for embodiments of the claimed method where the solid fat is used as a solvent for the one or more active ingredients, it does not reasonably provide enablement for the scope of claim 1 as written, that is, to a method of preparing nanoscale or amorphous particles using any ratio of one or more active ingredients to solid fat. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to prepare nanoscale or amorphous particles according to the method of claim 1 using any ratio of one or more active ingredients to solid fat, commensurate in scope with the claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).<sup>1</sup>

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC

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<sup>1</sup> As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to a method for preparing nanoscale or amorphous particles. The relative skill of those in the art is high, that of a Masters or PhD.

2. The breadth of the claims

The breadth of the claims include a method for preparing nanoscale or amorphous particles comprising the steps of (1) preparing a mixture comprising one or more active ingredients and solid fat in any relative ratio and (2) pressurizing the mixture to the critical pressure or more by adding the gas of a supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat

together with the gas of the supercritical fluid.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for preparing nanoscale or amorphous particles using any ratio of one or more active ingredients and solid fat. No reasonably specific guidance is provided for preparing particles according to claim 1, other than the method of claim 1 wherein solid fat is used as a solvent for the one or more active ingredients (i.e. in large excess to the one or more active ingredients). The latter is corroborated by the working examples. The claims encompass adding a large excess of one or more active ingredients to solid fat. For illustrative purposes only, the claims encompass adding 99 wt% active ingredient to 1 wt% solid fat. In this embodiment, upon extraction of the solid fat, it is reasonable that nanoscale or amorphous particles would not be produced as the mixture comprising 99 wt% active ingredient would be mostly unchanged. By contrast, all of Applicant's examples are to using the solid fat as a solvent for the one or more active ingredients (i.e. in large excess to the one or more active ingredients).

4. The quantity of experimentation necessary

In the absence of experimental evidence, no one skilled in the art would accept the assertion that nanoscale or amorphous particles could be produced according to the method of claim 1 using any ratio of one or more active ingredients to solid fat.

Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the invention claimed in the patent a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is indefinite for the following two reasons:

(1) It is unclear how there can be a “co-solvent” in claim 1 as there is no first solvent in claim 1. Co-solvent implies that it is added to a first solvent. There is no solvent disclosed in claim 1. The solid fat may be considered a solvent, but there is no limitation in claim 1 that it is used as a solvent. It may be used in any amount in claim 1.

(2) It is unclear in what way the “co-solvent is further used in step (1)”. Is the mixture comprising one or more active ingredients and solid fat dissolved in the co-solvent? Could the co-solvent be used to wash the mixture? Is the active ingredient prepared in or isolated from a co-solvent? Is the solid fat prepared in or isolated from a co-solvent? There are many ways the co-solvent could be “further used” in step (1) and the skilled practitioner would not know based on the current claim language which use of the co-solvent Applicant is trying to claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 8-11, and 14-18 are rejected under 35 U.S.C. 102(a) and (e) as being anticipated by US 20040043076 ('076). '076 discloses a method for preparing amorphous particles comprising bringing a particulate active ingredient and a coating agent, such as solid fatty acid esters (a solid fat), into contact with stirring, in supercritical CO<sub>2</sub>, adjusting the temperature and pressure of the supercritical CO<sub>2</sub> to deposit the coating agent onto the particulate active ingredient, and subsequently removing the supercritical fluid (abstract; paragraphs 17 and 33; claims). Although '076 does not teach that excess solid fatty acid ester is extracted into the supercritical fluid, owing to the solubility of the solid fatty acid ester in supercritical CO<sub>2</sub>, it is reasonable that excess solid fatty acid ester would be extracted from the active ingredient. The above method reads on (1) preparing a mixture comprising one or more active ingredients and solid fat and (2) pressurizing the mixture comprising one or more active ingredients and solid fat to the critical pressure or more by adding the gas of a

supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat together with the gas of the supercritical fluid.

Fatty acid esters include C8 to C38 fatty acid esters such as ethyl palmitate (paragraph 33). The supercritical CO<sub>2</sub> temperature may be 30°C and the pressure may be 280x10<sup>5</sup> Pa (276 atm) (paragraph 14). The active ingredient may be one or more proteins (paragraph 37).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 8-11, and 14-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6471993 ('993) in view of US 20060035350 ('350). '993 discloses a method for preparing a polymer matrix comprising the steps of (1) preparing a mixture comprising a polymer in a solvent, such as ethanol, one or more active ingredients, and a solid porogen (see abstract; col 4, lines 60-3; col 6, lines 17-21) and (2) extracting the solid porogen with an appropriate means to form a polymer matrix (see col 11, lines 62-67). One possible porogen are triglycerides (see col 13, lines 40-48; Table 1). One possible porogen extraction means is extraction by supercritical carbon dioxide (see col 11, lines 62-67).

Although '993 does not explicitly teach using supercritical carbon dioxide to extract triglycerides, US 20060035350 ('350) teaches that supercritical carbon dioxide is a common solvent for triglycerides (see paragraph 9).

Accordingly, it would have been obvious to use supercritical carbon dioxide to extract triglyceride porogens in the method of '993 because teaches that supercritical carbon dioxide is a common solvent for triglycerides thus teaching equivalency of other solvents specifically used by '993. The resulting method would be a method comprising the steps of (1) preparing a mixture comprising one or more active ingredients and solid

fat and (2) pressurizing the mixture comprising one or more active ingredients and solid fat to the critical pressure or more by adding the gas of a supercritical fluid into the mixture, and then removing the solid fat from the mixture by releasing out the solid fat together with the gas of a supercritical fluid. It would have been further obvious to optimize the temperature and pressure of the extraction process as temperature and pressure are routinely optimized parameters when using and maintaining supercritical fluids. The above method is identical to Applicant's claimed method. Regarding the limitation "for preparing nanoscale or amorphous particles", this does not require the particles to have any particular size or composition, other than they must be either nanoscale or amorphous. The matrix of '993 as a whole could be considered as a particle, and this matrix is amorphous. In another interpretation, polymer particles may be used in preparing the matrix and it is reasonable that at least a portion of the polymer particles remains particular when the method is finished. Such particles would be non-crystalline (amorphous). '993 also teaches adding several additive particles into the matrix (see '993, entire document). There only needs to be two nanoscale or amorphous particles present in the final product to read on "a method for preparing nanoscale or amorphous particles".

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson  
Examiner  
AU 1618

July 30, 2010